

## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| PPLICATION NO.            | FILING DATE        | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO |  |
|---------------------------|--------------------|----------------------|-----------------------|-----------------|--|
| 09/592,007                | 06/12/2000         | Francis Tufaro       | 08582/009002 4193     |                 |  |
| 21559 75                  | 90 11/07/2003      |                      | EXAMINER              |                 |  |
|                           | CLARK & ELBING LLP |                      |                       | SCHULTZ, JAMES  |  |
| 101 FEDERAL<br>BOSTON, MA |                    |                      | ART UNIT PAPER NUMBER |                 |  |
| ,                         |                    |                      |                       |                 |  |

DATE MAILED: 11/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| · · · · · · · · · · · · · · · · · · ·   | Application No.  | Applicant(s)  |                                      |  |  |  |
|---|--|---|--------------------------------------|--|--|--|
| Advisory Action   | 09/592,007   | TUFARO ET AL.   |                                      |  |  |  |
| 7.447.66.y 7.66.76.7  | Examiner   | Art Unit  |                                      |  |  |  |
|   | J. Douglas Schultz   | 1635  |                                      |  |  |  |
| Th MAILING DATE of this communication appe  | ars on the cov r sh et with the c  | rrespondence add  | ress                                 |  |  |  |
| THE REPLY FILED 02 September 2003 FAILS TO PLA Therefore, further action by the applicant is required to a final rejection under 37 CFR 1.113 may only be either: (1 condition for allowance; (2) a timely filed Notice of Appearance (RCE) in compliance with 37 CFR 1.114.  | void abandonment of this applice it is applicated an applicate it is applicated an applicated an applicated an applicated applicated applicated an applicated applica | cation. A proper rep<br>ch places the applic            | oly to a<br>cation in                |  |  |  |
| PERIOD FOR RE   | PLY [check either a) or b)]  |   |                                      |  |  |  |
| a) The period for reply expiresmonths from the mailing of   |  |   |                                      |  |  |  |
| b) The period for reply expires on: (1) the mailing date of this Adverse event, however, will the statutory period for reply expire later the ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS 706.07(f).   | an SIX MONTHS from the mailing date of FILED WITHIN TWO MONTHS OF THE  | f the final rejection.<br>E FINAL REJECTION. S          | See MPEP                             |  |  |  |
| Extensions of time may be obtained under 37 CFR 1.136(a). The dath have been filed is the date for purposes of determining the period of extens 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened (b) above, if checked. Any reply received by the Office later than three moleanned patent term adjustment. See 37 CFR 1.704(b). | sion and the corresponding amount of the statutory period for reply originally set in  | fee. The appropriate ext<br>the final Office action; or | ension fee under (2) as set forth in |  |  |  |
| 1. A Notice of Appeal was filed on <u>02 September 2003</u> . Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.   |  |   |                                      |  |  |  |
| 2. The proposed amendment(s) will not be entered because:   |  |   |                                      |  |  |  |
| (a) They raise new issues that would require further consideration and/or search (see NOTE below);  |  |   |                                      |  |  |  |
| (b) They raise the issue of new matter (see Note below);  |  |   |                                      |  |  |  |
| (c) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  |  |   |                                      |  |  |  |
| (d) they present additional claims without cancel NOTE:   | ing a corresponding number of t  | finally rejected clain                                  | ns.                                  |  |  |  |
| 3. Applicant's reply has overcome the following reject  | tion(s):   |   |                                      |  |  |  |
| 4. Newly proposed or amended claim(s) would canceling the non-allowable claim(s).   | be allowable if submitted in a s   | eparate, timely filed                                   | l amendment                          |  |  |  |
| 5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: <u>See Continuation Sheet</u> .   |  |   |                                      |  |  |  |
| 6. The affidavit or exhibit will NOT be considered bed raised by the Examiner in the final rejection.   | cause it is not directed SOLELY  | to issues which we                                      | re newly                             |  |  |  |
| 7. For purposes of Appeal, the proposed amendment explanation of how the new or amended claims we   |  |   | and an                               |  |  |  |
| The status of the claim(s) is (or will be) as follows:  |  |   |                                      |  |  |  |
| Claim(s) allowed:   |  |   |                                      |  |  |  |
| Claim(s) objected to:   |  |   |                                      |  |  |  |
| Claim(s) rejected:  |  |   |                                      |  |  |  |
| Claim(s) withdrawn from consideration:  |  |   |                                      |  |  |  |
| 8. The proposed drawing correction filed on is  | a) approved or b) disapp   | proved by the Exam                                      | iner.                                |  |  |  |
| 9. Note the attached Information Disclosure Statemer  | nt(s)( PTO-1449) Paper No(s)   |   |                                      |  |  |  |
| 10. Other:  |  |   |                                      |  |  |  |
|   |  |   |                                      |  |  |  |
|   |  |   |                                      |  |  |  |

Continuation of 5. does NOT place the application in condition for allowance because: Applicants present no arguments that have not been addressed in the advisory action dated October 16, 2002, and the final Office action dated February 26, 2003. Briefly, applicants' arguments center on the assertion that none of the references provide motivation for their combination. For example, applicants state that "There simply is no suggestion or motivation to introduce viruses into cells in vivo from Hodgson, as was stated in the Office Action". However, the following is a quote from the introduction of Hodgson, at page 339: "One approach to improving gene therapy is to combine their lative safety and efficiency of transfection with the permanency of stable transduction methods. This could be done either by combining purified viral enzymes, nucleic acids, and transfection reagents (comprising a synthetic viral particle) or alternatively by starting with particles and enhancing transduction frequencies biochemically. The latter approach is potentially easier to accomplish. For example, adenovirus has been used to deliver DNA (on the outside of viral particles) to cells via the endosomal pathway and retroviral vectors have been modified via the attachment of ligands for cellular receptors (such as peptide hormones and by the incorporation of chimeric envelope glycoproteins or chemically coupled ligands in order to facilitate their attachment and entry into cells. As is evident from this passage, Hodgson clearly contemplates and discusses gene therapy, i.e. in vivo whole animal administration of viral particles containing DNA. Applicants arguments are thus not considered convincing.

SEAN MCGARRY
PRIMARY EXAMINER
1635